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# A PROSPECTIVE OBSERVATIONAL STUDY ON COMPLIANCE TO A 14-DAY ZINC TREATMENT FOR ACUTE DIARRHEA IN UNDER 5 YEARS CHILDREN? ARE WE FAILING AT IT

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**ABSTRACT** **Background:** Over a million children die as a result of diarrhea and dehydration every year. Provision of zinc in addition to low osmolarity ORS is still ineffectively implemented. **Methods:** A prospective observational study was conducted on 101 children under 5 years of age with acute gastroenteritis to assess their compliance with zinc therapy from Jan 2023 to March 2023 visiting Pediatric Outpatient department of Tertiary Care Hospital ,Lucknow. They were prescribed nationally advised WHO ORS and zinc treatment regimen (ie, 10 mg/day for ages 2–6 months and 20 mg/day for ages 7–59 months for 14 days) Our objective was to study the compliance of 14 day Zinc supplementation ,to find the reasons for non-compliance ,to find the statistical diffference in repeated episodes of diarrhea over the next 3 months among the two groups . A p-value of <0.05 was considered statistically significant **Results:** The mean age was 18.58±13.41 months, 39.60% of patients completed the full 14 days of zinc therapy. Zinc was administered for an average of 8.28±2.81 days. Further episodes of diarrhoea occurred in 10.65% of the subjects. In general, diarrhoea ended (63. 9%), ignorance (14.75%), and vomiting(11.5%) were the main causes of termination. **Conclusions:** The compliance of Zinc supplementation is very poor among caregivers of children suffering from acute diarrhea. The results show that the syrup formulation is suitable, although more work is needed to improve adherence. These results further emphasise the significance of ensuring zinc duration adherence while also addressing care givers propensity to stop medication once a child seems to be recovering from an acute diarrheal episode.

**KEYWORDS :** Acute diarrheal , Acute gastroenteritis, Compliance, Oral rehydration solution, Zinc syrup

## INTRODUCTION

Despite the widespread use of oral rehydration treatment ,acute diarrheal illnesses continue to be a major cause of childhood morbidity and mortality worldwide in countries with poor resources.[1]

Rotavirus was the main etiological agent in 2016 and diarrhoea was the sixth highest cause of death in children under the age of five.[2]

In order to treat children under the age of five who have acute diarrhoea, the World Health Organisation (WHO) and the United Nations Children's Fund (UNICEF) suggested routine administration of zinc on May 8, 2004.[3] To lessen the severity of the episode and prevent further occurrences in the ensuing two to three months, the World Health Organisation (WHO) and UNICEF recommend daily 20 mg zinc supplements for 14 days for children with acute diarrhoea, and 10 mg per day for infants under six months old. This significantly reduces morbidity. Zinc therapy is an easy, affordable, and important tool for treating diarrhea among children.[4]

Low osmolarity ORS and zinc have been incorporated into diarrhoea management plans in many countries, but there is still a gap between policy change and efficient programme implementation, with relatively few children currently receiving the necessary care.[5,6]

The acceptance of zinc and adherence to therapy are very low, despite the Government of India's initiative to provide zinc in addition to low osmolarity ORS through the public health system, as part of the National Rural Health Mission. The main goal of our study was to assess 14-day zinc therapy compliance in children with acute gastroenteritis.

Finding the reasons for zinc therapy non-compliance and comparing the recurrence of diarrhoea over the course of 3 additional months in children with strong compliance versus poor compliance were secondary goals. There is a paucity of knowledge regarding the present acceptability of and compliance with zinc supplementation recommended at the health facility among children with diarrheal illnesses, as well as the motivation of their mothers to provide the same continuous 14 days.

## METHODS

After receiving ethical approval, a prospective observational study was carried out on 101 children under 5 years age for acute gastroenteritis (loose stools with or without dehydration symptoms) in the outpatient paediatric department . The study was conducted beginning in January 2023 and continued until the necessary number of kids were enrolled and their follow-up was finished.

According to a study by Valekar SS, 16% of Indian children took their 14-day zinc supplements as prescribed. With an expected prevalence of 16%, absolute precision of 10%, and an alpha error of 5, 103 patients were determined to be the necessary sample size. Children who already have immune deficiencies, neonates, those with systemic bacterial infections, and diarrhoea lasting more than 14 days at presentation were excluded. Enrolled children were started on WHO ORS and zinc in the form of syrup (ie, 10 mg/day for ages 2–6 months and 20 mg/day for ages 7–59 months for 14 days. Parents/ caregivers were counseled and advised to continue it for 14 days.

On days 3 and 8, phone calls were used to check in with them. On day 14, a follow-up visit to the OPD was made, as well as three months after their enrollment date. Data on the duration of ORS, the resolution of diarrhoea, and zinc supplementation were gathered. Our objective was to study the compliance of 14 day Zinc supplementation ,to find the reasons for non-compliance ,to find the statistical diffference in repeated episodes of diarrhea over the next 3 months among the two groups .

A p-value of <0.05 was considered statistically significant. IBM SPSS version 22 was used for statistical analysis.[7]

Informed consent was taken from caretakers of children suffering from diarrhea

## RESULTS

The final analysis covered 101 participants in total,2 were dropouts 43 (42.57%) of the participants in the study were male, and the remaining 58 (57.42%) were female. The average age was 18.58±13.41 months Weight in kilogrammes averaged 11.37± 11.07. 40 (39.60% %) of the 101 participants received a zinc dosage for 14 days. The average number of days that participants took ZN was 8.28±2.81 days Out of 61 who didn't complete 14 day therapy, 39 (63. 9%) participants discontinuing because their diarrhoea had stopped, 9 (14.75%) participants for lack of knowledge and ignorance, 7(11.5%) participants due to vomiting,4 (6.5%) due to unpalatable taste and the remaining 2(3.27%) participant due to repeated diarrhea . Additional episodes of diarrhoea occurred in 16(15.84%) of the subjects (N=101; Table 1).

After 14 days of zinc therapy, out of 40 patients,1 (2.5%) study participants experienced additional bouts of diarrhoea, and the difference between the two groups was statistically significant (p-value <0.003)

## DISCUSSION

In our study ,there were 101 children, and 41.74 percent of them were male.

The study group's average age was18.58±13.41 months, and its average weight was11.37± 11.07 kg. Similar to this study, Lamberti LM et al.'s study from Uttar Pradesh had a mean age of 17.7 months and a gender distribution of study subjects that was nearly equal

(42.5% men).11 However, in their study, 89.3% of participants took zinc tablets, whereas 11.5% used zinc syrup. In our study, the average daily intake of zinc was 8.28±2.81 days days, while 10.7 days, according to Lamberti LM et al.[9]

Similar to our study, Lamberti LM et al. reported that 47.8% of patients continued treatment for the full 14 days.

In contrast to our study, a randomised effectiveness trial carried out in outpatient health facilities of six sites in five countries—namely, Fortaleza (Brazil), Addis Adaba (Ethiopia), Cairo (Egypt), Lucknow and Nagpur (India), and Manila (Philippines)—reported significantly higher compliance of 83.8%. 2,002 children between the ages of 2 and 59 months participated. The intervention involved comparing ORS and zinc (20 mg orally, once day for 14 days) in the zinc group to ORS alone in the control group. [10]

By taking one tablet daily that had been fully dissolved in a modest amount of water, Ahmed S. et al. found that 62% of the kids successfully completed a full 10-day course of zinc treatment (good compliance).[8]

According to their analysis, there is a 63% increased chance of poor zinc compliance if the father stays at home with the family [OR = 1.63 (95%CI; 1.09, 2.46) p = 0.019]. After controlling for confounders, 33% of kids continued to take zinc supplements despite vomiting [OR = 0.67 (95%CI; (0.47, 0.97, 0.032)].

In our study, there were additional episodes of diarrhoea in 15.84%% of patients. Zinc has been used to treat a variety of medical conditions, although side effects have been recorded in both adults and adolescents, including nausea and vomiting.[8]

It was found that bundling zinc with ORS utilising a pouch with instructional messaging improved adherence to the medication in a cluster-randomized controlled study conducted in 2015 in eight districts of Ethiopia. Compared to the "central bundling" strategy, "HC level bundling" is more CE.[4]

In our study trial, most participants (63. 9%) terminated when their diarrhoea ceased. Ignorance was the cause of discontinuance in 14.75% of the individuals. In their study, Lamberti LM et al. also noted that 27.1% of subjects' children received further treatment while 69.5% of subjects' children stopped receiving treatment as they healed.[9]

In order to increase efforts to minimise child mortality from diarrhoea, the Ministry of Health and Family Welfare in India has launched the Intensified Diarrhoea Control Fortnight (IDCF). At the state, district, and village levels, increased community awareness efforts on hygiene and promotion of ORS and Zinc treatment will be carried out over the fortnight.

In our study,only 39.60% % of participants completed the whole 14-day zinc treatment regimen. Zinc was administered for an average of8.28±2.81 days days. sthe study, zinc therapy is a straightforward, affordable, and essential method for treating children's diarrheal bouts. This study is constrained by its reliance on The fact that this study relied on carer reports to estimate provider recommendations regarding zinc treatment dose and duration limits its applicability. The fact that our investigation was done in a single centre limits the findings' generalizability.

The reduced sample size may be to blame for the lack of statistical significance of several differences between the research groups. Due to the study's limited sample size, the role of potential confounding important variables could not be determined. Large-scale multicentric studies are required to improve the quality of the information that is currently accessible about the Indian population.

## CONCLUSION

Only 39.60% of the patients in this study finished the whole 14-day zinc treatment course. Our research demonstrates that Indian carers typically do not follow the zinc therapy regimen for diarrhoea. Programmes aiming to increase the use of zinc for treating paediatric diarrhoea should train medical staff on how to communicate dosage recommendations to parents. These findings indicate that the syrup formulation is appropriate, but that additional effort is required to increase adherence. Our data also highlight the importance of counselling to ensure that zinc duration is followed, as well as the tendency of caretakers to discontinue medication as soon as a child appears to be healing from an acute diarrheal episode.

**Table 1: Descriptive Analysis Of Parameter In The Study Population.**

| Parameters Summary | |
|---|---|
| Gender N (%) | |
| Male | 43 (42.57%) |
| Female | 58 (57.42%) |
| Age in months (Mean±SD) | 18.58±13.41 |
| Weight in Kg (Mean±SD) | 11.37± 11.07 |
| Taken for 14 days N (%) | |
| Yes | 40 (39.60% %) |
| No | 39 (37.86%) |
| No of days Zn taken (Mean ± SD) | 8.28±2.81 days |
| Reason for discontinuation (N=40) N (%) | |
| Diarrhoea stopped | 39 (63. 9%) |
| Ignorance | 9 (14.75%) |
| Repeat diarrhea | 2(3.27%) |
| Unpalatable | 4 (6.5%) |
| Vomiting | 7(11.5%) |
| Further Episodes of Diarrhea (N=101) | |
| Yes | 16(15.84%) |
| No | 85(84.16%) |

| Taken for 14 days | Further episodes of diarrhoea | | Chi-square | Fisher exact p-value |
|---|---|---|---|---|
| | Yes | No | 8.8424 | <0.003 |
| Yes (N=40) | 1 (2.5%) | 39 (97.5%) | | |
| No (N=61) | 15 (24.60%) | 46(75.40%) | | |

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